AMERICAN BENEFITS COUNCIL

June 27, 2007

The Honorable Edward Kennedy
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I am writing on behalf of the American Benefits Council to express our support for legislation that establishes a regulatory pathway for the approval of follow-on biologics (also known as biogenerics or biosimilar products). The American Benefits Council represents employers and other organizations that either sponsor or administer health and retirement benefits covering more than 100 million Americans.

We welcome your leadership in working with your colleagues to find a consensus approach to resolving this difficult issue. We believe, as you do, that carefully balanced legislation is essential in order to ensure that the Food and Drug Administration (FDA) has the clear authority it needs to approve follow-on biologics while fully protecting patients who increasingly depend on these therapies for the treatment of complex and often life-threatening diseases. We also believe that the intellectual property of those who are the innovators in biologics research and development should be protected by providing a reasonable period of time for the exclusivity of their data. Finally, we believe that the FDA should have broad discretion in determining the extent of any testing, clinical trials, studies or other scientific evidence or data needed for its approval of follow-on biologics. The agency should be able to fully exercise its judgment as to the specific evidence needed for approval of a particular biologic product.

Employers recognize that biologic therapies will be increasingly important for the treatment and cure of diseases which millions of Americans confront today and may face in the future. We all have a strong stake in encouraging the continued development of truly innovative biologic therapies while also encouraging competition in the pharmaceutical marketplace. Legislation that both protects those who take the financial risk to bring new therapies to market and establishes a responsible regulatory pathway within the FDA for the approval of follow-on products by competitors should be a high priority for this Congress. We look forward to working with you and your colleagues on this important issue.

Sincerely,

James A. Klein

James A. Klein
President